NIH Consensus Development Program

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Introduction

The Consensus Development Program (CDP) is an unbiased, independent, evidence-based assessment of complex medical issues and is conducted by the National Institutes of Health (NIH). The program has operated since 1977. Each conference is jointly sponsored and administered by one or more Institutes or Centers (ICs) of NIH and by the Office of Medical Applications of Research (OMAR) in the Office of the Director of NIH. Depending on the topic, other Federal agencies with biomedical components may join in sponsoring a CDP conference. In conjunction with each conference, the Agency for Healthcare Research and Quality (AHRQ) provides a systematic review of literature on the conference topic through one of its Evidence-Based Practice Centers.

The purpose of a CDP conference is to evaluate the available scientific information on a biomedical issue and develop a statement that advances understanding of the issue under consideration and will be useful to health professionals and the public. The panel is an independent, broad-based, non-Department of Health and Human Services (DHHS), nonadvocacy group with appropriate expertise. The panel listens to the scientific data presented by invited experts and comments from the general public. The panel weighs the information and then composes a statement that addresses a set of predetermined questions. This statement is an independent report of the panel and is not a policy statement of NIH or the Federal Government and is not an advisory body to NIH.

Conference statements and recommendations focus on medical safety and efficacy, although they may refer to related issues (e.g. economic, sociologic, legal and ethical) that help to provide a context for the issue. CDP conferences are particularly useful for providing guidance when a controversy exists over preventive, therapeutic, or diagnostic options, or when the issue is of public as well as professional interest.

A consensus statement is based on publicly available data and information. It is not intended as a legal document, practice guideline, or primary source of detailed technical information. Rather, the statement reflects the views of a panel of thoughtful people who understand the issue before them and who carefully examine and discuss the scientific data available on the issue. The creative work of the panel is to synthesize this information, along with sometimes conflicting interpretations of the data, into clear and accurate answers to the questions posed to the panel. The statement may reflect uncertainties, options, or minority viewpoints. Following the conference, the consensus statement receives wide circulation through both lay and medical media. Conference proceedings are webcast live (http://consensus.nih.gov) and archived for later viewing.

The basic principles governing the conduct of a CDP conference follow:

1. A broad-based, non-DHHS, nonadvocacy, independent panel is assembled to give balanced, objective, and knowledgeable attention to the topic. Panel members are carefully screened to exclude anyone with scientific or financial conflicts of interest (see Selecting the Panel).

2. Invited experts present data to the panel in public sessions, followed by inquiry and discussion. The panel then meets in executive session to prepare the statement.

3. Four to five predetermined questions define the scope and direction of the conference. These questions are widely circulated and are known to all conference participants. The principal job of the panel is to develop responses to them.

4. A systematic literature review is prepared for use by the panel in addressing the questions. The review is prepared by the Agency for Healthcare Research and Quality (http:/www.ahrq.gov) through one of several Evidence-based Practice Centers.

5. Near the end of the conference a draft conference statement is prepared by the panel in executive session and is then presented in plenary session. Following public discussion the panel may modify the statement as they deem appropriate and the resulting statement is posted on the website (http://consensus.nih.gov) as DRAFT and is usually finalized in 4-8 weeks postconference.

6. The consensus statement is widely disseminated to achieve maximum impact on health care practice and medical research.

The Topic

Topics for CDP conferences may be suggested by ICs, OMAR, other Government health agencies, Congress, and the public. Final selection of a topic is made when agreement is reached between a sponsoring IC and OMAR. Cosponsorship by additional ICs or other Government health agencies is then invited.

A CDP conference topic must meet the following criteria:

- The topic should have public health importance; it should affect or broadly apply to a significant number of people. The severity of the problem (morbidity and mortality) and the feasibility of intervention are key considerations
- Controversy or unresolved issues can be clarified, or a gap between current knowledge and current practice may be narrowed.
- The topic must have an adequately defined and available base of scientific information from which to answer the conference questions and resolve controversies.
- The topic should be amenable to clarification on technical grounds, and the outcome should not depend primarily on subjective judgments of the panelists.

Additional elements desirable in selecting a conference topic are the impact on health care costs and a high degree of public interest. After a topic is judged to meet the selection criteria, planning and implementation of the CDC may proceed. If a suggested topic does not have an adequately defined and available base of scientific information, conference planning and implementation may still proceed. However, rather than being designated as a Consensus Development Conference, the conference will be designated as a State-of-the-Science Conference. The primary goal of a State-of-the-Science Conference is to summarize the evidence and recommend directions for further research. Otherwise, the State-of-the-Science Conference closely follows the same process used for a Consensus Development Conference.

The Staff

OMAR and IC staff members are responsible for conference logistics, publicity, continuing medical education accreditation, and any other tasks.

The sponsoring IC nominates an IC coordinator, who usually chairs the planning committee and serves as the IC representative in managing the conference. The IC coordinator should be knowledgeable in the area of science under consideration.

OMAR assigns a senior staff member to serve as OMAR coordinator. This person works with the IC coordinator and other IC representatives in organizing the conference and also serves on the planning committee.

The information office of the IC assigns a staff person to assist the OMAR Director of Communications in planning conference publicity and media coverage as well as dissemination of the consensus statement. The IC and OMAR representatives serve on the planning committee.

The Initial Planning

The IC coordinator, the OMAR coordinator, and other appropriate IC and OMAR staff members review the conference topic, review the general scientific base supporting the topic, and agree on whether the topic meets the criteria for a CDP conference. After acceptance of the topic, they outline general conference objectives and establish a timetable for conference planning. The coordinators identify other interested organizations within and outside NIH and consider appropriate roles for them, which may include cosponsorship of the conference. Representatives of other ICs and organizations may be asked to join the planning process.

The OMAR coordinator, the IC coordinator, an AHRQ representative, and representatives from other interested organizations hold an organizational meeting. The scope and approximate date of the conference are tentatively determined, and a panel chairperson is nominated. The panel chairperson takes part in all major conference planning activities. Additionally, two to four persons from the general research community who are not DHHS employees and who are knowledgeable about the conference issues are nominated as members of the planning committee.

The coordinators develop a travel and conference budget. The OMAR coordinator arranges logistical support for the CDC through a non-Government contractor (see Logistical Support).

The Panel Chairperson

The panel chairperson should be a knowledgeable and prestigious figure in the field of medical science under consideration but should not be identified with an advocacy position on the conference topic or with research that might be presented to answer conference questions.

The individual selected as panel chairperson is responsible for chairing the plenary session of the conference, the panel's deliberations, and the press conference, and thus should be a strong public moderator and a skillful leader of group discussions.

The panel chairperson, like other members of the panel, must be a U.S. citizen and must not be an employee of the Department of Health and Human Services (NIH, FDA, CMS, etc.), must not have financial or career interests in the topic, and not hold advocacy opinions relevant to the conference.

The Conference Planning Committee

The conference planning committee has six major functions: (1) to draft the conference questions, (2) to draft the conference agenda, (3) to nominate potential conference speakers, and (4) to nominate potential panel members (5) title the conference and (6) sets the date for the conference.

The planning committee is composed of the CDP conference panel chairperson and representatives of the sponsoring IC, OMAR, and other interested NIH ICs. Other interested Federal agencies may also participate. Members of the planning committee also include several recognized experts from the research community who are not Federal employees. Representatives from AHRQ attend the planning meeting. The planning committee is usually chaired by the IC coordinator, although the IC director or another representative may serve in this role.

Planning committee members, except for the panel chairperson, may not serve on the CDP conference panel itself. Planning committee members may serve as speakers at the conference, however. Disclosure of any scientific or financial interest in the conference topic is requested of non-Federal planning committee members.

Drafting the Conference Questions
A CDP conference is structured around key questions posed to the panel. Ordinarily, four to six questions are posed, including questions on the efficacy, risks, and clinical applications of a technology, plus a final one on directions for future research. These questions determine the scope and substance of the conference. They should be framed so that answers can be derived from scientific information presented by the speakers and derived from the medical literature. The phrasing of the questions should not allow for responses based solely on subjective judgments or opinions of the panel. Questions should be straightforward and concise.

Drafting the Conference Program

The CDC is usually held over a 2 1/2 day-period. The first day and a half consist of a plenary session in which invited speakers present evidence, followed by open discussion among speakers, panelists, and audience. On the evening of the first day, the panel meets in executive session to begin to draft the consensus statement, which is a response to the conference questions. On the afternoon of the second day, the panel again meets in executive session and completes a draft of the consensus statement. The following morning the draft statement is presented in a public session for audience comment. On the basis of these comments the statement may be modified by the panel in a final executive session held the same day.

The conference program should be broad enough to encompass the body of scientific information essential to answering the conference questions and should include divergent scientific and medical views. Presentation topics should be selected so that speakers can use the style and format appropriate to scientific meetings; that is, the presentations should be based on analysis of data, with methodology fully explained and citations to the relevant scientific literature provided. The intent is that conference speakers present information to the panel and the audience as scientific experts, not as advocates of particular answers to specific questions.

An appropriate balance between formal presentations and discussion should be provided in the time allotted.

Selecting Conference Speakers

Speakers are selected for their scientific expertise and may include clinical investigators and basic scientists as well as general authorities in the field. Where differences of scientific opinion exist, care should be exercised to include the presentation of opposing data and interpretations. Speakers are asked to confine their presentations to the scientific topic that they have agreed to address and to be certain to present all relevant data and information. Speakers are expected to provide abstracts of their presentations.

Selecting the Panel

A range of expertise on the panel is important to the panel's ability to deliberate on the varied scientific material presented. This diversity enhances the credibility of the statement. The panel should represent various sectors of professional and community life, including each of the following four general categories:

- Research investigators in the field--that is, scientists who are active in the area under consideration
- Health professionals who use the technology, including practicing physicians, dentists, psychologists, nurses, or other health care providers
- Methodologists, such as epidemiologists, biostatisticians, and clinical trialists
- Public representatives, such as ethicists, lawyers, theologians, economists, public interest group or voluntary health association representatives, consumers, and patients.

Panel members:

- must be U.S. citizens
- must not be employees of the Department of Health and Human Services (NIH, FDA, CMS, etc.),
- must not have financial or career interests (research interests) in the topic and
- may not hold advocacy opinions relevant to the conference

Panel members must be thoughtful, able to weigh evidence, and capable of collaborative work.The size of the panels has varied from 9 to 16 members, with 12 or 13 members found to be an effective number for a working group. The panel is not paid a fee or honorarium for their extensive efforts. They are however reimbursed for travel expenses related to the conference.

Conference Publicity

Conference publicity is planned and coordinated by the OMAR Director of Communications and the information office representative of the sponsoring IC. Publicity planning includes developing an information dissemination plan that:

- Identifies target audiences thought to have an interest in a particular conference so that an announcement of the meeting can be disseminated as widely as possible to all interested groups in a variety of media (for example, brochures, the Internet, professional journals, lay newsletters)

- Encourages interested parties to attend the conference and present testimony
- Outlines the publication of conference reports and papers
- Identifies organizations and publications to which the statement should be sent

Continuing Medical Education Credit

The NIH Office of Education is accredited to sponsor continuing medical education (CME) for physicians in Category I of the Physician's Recognition Award of the American Medical Association. Most CDC's average between 13 and 15 CME credits. OMAR is responsible for submitting the application for CME to the Office of Education of NIH.

Because the audience for a CDP conference may include groups other than physicians (for example, psychologists, dentists, or nurses), other types of continuing education may be appropriate. The application process for other types of continuing education may be initiated and handled at the discretion of the sponsoring IC.

The Consensus Development Conference

The conference panel holds a 1-day executive meeting approximately 1 month prior to the conference. The OMAR coordinator briefs the panel on the consensus development process and procedures. The panel reviews the collected and synthesized materials they have received up to that point. These materials include speaker abstracts, the AHRQ systematic literature review, overview publications selected by the Planning Committee, and other material that may have been submitted by the general public and health professionals. This review enables the panel to identify areas of particular controversy as well as areas where further information is needed. Proposed formats/outlines for answering the questions may also be discussed. Panelists may then discuss the areas in which they wish to probe individual speakers and outline their approaches to answering the conference questions.

The conference plenary sessions are moderated by the panel chairperson who ensures that speakers adhere to time limits, allows ample opportunity for scheduled discussion, and invites questions and comments from panelists and audience members, taking questions from panelists first. All plenary sessions, including the press conference, are broadcast on the Web.

The entire panel, working in subgroups, begins to draft the statement during the executive sessions. The panel should attempt to reach consensus on each question based on the scientific evidence presented. To produce a firm statement, the panel is encouraged to draw clear conclusions whenever feasible. If consensus cannot be achieved, minority or alternative views may be included.

The conference convenes again in plenary session on the morning of the final day, and the chairperson reads the initial draft of the conference statement which is then subject to review and comment by conference attendees. The panel adjourns following this session for a final executive session (approximately 3 hours), where it may revise the draft statement to reflect comments from the floor. The first 10 to 15 minutes of this final executive session are spent on reviewing the draft press release, which highlights the conclusions of the panel as set forth in the consensus statement. The press release is written by the OMAR Director of Communications and the IC information office representative, and is distributed at the press conference and disseminated nationwide.

A press conference is held after the final executive session, with the panel chairperson serving as spokesperson for the panel. Panel members are expected to remain at the meeting during the press conference, which usually lasts about an hour. The panel chairperson opens the press conference with a brief summary (about 5 minutes) of the panel's findings in lay language. Subsequently, the floor is opened to questions from the media. The panel members and the chairperson should participate in responding to press questions. The panel chairperson and the other panel members should be available for a brief time after the press conference to answer questions and to be interviewed by newspaper, radio, or television reporters.

Following the conference, panel revisions of the consensus statement are promptly incorporated into a final draft and sent to the panelists for a final review. The statement is then sent to the chairperson for final approval. Following this process, the statement is considered final.

Conference Results

Consensus Development Conferences often receive attention from the media. The major print and broadcast media may report the results of a CDP conference, which serves to focus attention on the topic and the conference statement.

The draft consensus statement is posted to the Consensus Program Web site, http://consensus.nih.gov, immediately after the conference. The panel's final statement is posted to the Web four to eight weeks later.

The consensus statement is printed by OMAR and distributed to Federal health agencies, private sector health care organizations, directors of continuing medical education at American Hospital Association member hospitals, deans of medical schools, directors of State and county medical societies, and directors of HMOs and PPOs. The consensus statement is also sent to targeted individuals and organizations.

The statement is sent to an appropriate medical journal for possible publication. In addition, OMAR places notices in numerous professional journals announcing the availability of the statement. On several occasions the consensus statement, along with selected papers from a CDC, have been published as a supplement to a medical journal or as a monograph. OMAR also supports a clearinghouse facility to respond to public requests for the statement and for other conference materials.

Logistical Support

OMAR provides travel and management assistance throughout the planning and conduct of a CDC through a logistical support contract. The contractor assigns one or more individuals to work with the IC and OMAR coordinators from the beginning of the planning process through completion of the conference to the final distribution of the consensus statement.

The expenses of planning committee members, panel members, and conference speakers are paid by OMAR through the contractor.

The CDC budget developed by OMAR coordinators governs the expenditure of funds to the logistical support contract.

For additional information on the NIH Consensus Development Program, contact the Office of Medical Applications of Research, National Institutes of Health, 6100 Executive Blvd. Room 2B03, Bethesda, Maryland 20892; phone number (301) 496-1144.